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Award Number: W81XWH-05-2-0015

TITLE: Facilitating Smoking Cessation and Preventing Relapse in Primary Care:
Minimizing Weight Gain by Reducing Alcohol

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REPORT DATE: January 2009

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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REPORT DOCUMENTATION PAGE				<i>Form Approved</i> OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE (DD-MM-YYYY) 01-01-2009		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 27 DEC 2007 - 26 DEC 2008	
4. TITLE AND SUBTITLE Facilitating Smoking Cessation and Preventing Relapse in Primary Care: Minimizing Weight Gain by Reducing Alcohol Consumption				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-05-2-0015	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Mark B. Sobell, Ph.D.; COL Alan Peterson, Ph.D.; Linda C. Sobell, Ph.D. MAJ Christopher Hunter, Ph.D.; MAJ Christine Hunter, Ph.D. E-Mail: sobellm@nova.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Nova Southeastern University Fort Lauderdale, Florida 33314				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT This project is evaluating a brief smoking cessation intervention for use in primary care settings. The Brief Counselor Assisted Program (BCAP) combines motivational interviewing, behavioral counseling and nicotine replacement therapy [NRT; nicotine patch and bupropion (Zyban)] with an emphasis on reducing alcohol consumption as a strategy for minimizing smoking cessation related weight gain. Participants are randomly assigned to BCAP or to a Self-Guided Program (SGP) where they receive NRT and a pamphlet discussing change strategies for tobacco cessation, minimizing weight gain, and how to plan for and deal with possible relapses. Participants in BCAP have two clinic appointments and two phone counseling sessions. Current smokers in either group at 3-month follow-up, blocked by original group assignment, are randomized to receive either no further counseling or to attend a clinic booster session focusing on dealing with their individual obstacles to change. All participants will be followed up for 12 months. As of December 9, 2008, a total of 317 participants had entered the study, 158 in the BCAP group and 159 in the SGP group. 3-month follow-up has been completed on 91.5% of the 305 participants due for that follow-up and 90.0% of the 290 participants due for 6-month follow-up. Our focus is now on completing the treatment for the last participants, gathering follow-up data, and data entry and verification.					
15. SUBJECT TERMS Smoking Cessation, Weight, Alcohol, Stepped Care, Primary Care.					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 11	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

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Annual Report Award Number W81XWH-05-2-0015

Introduction

This report summarizes progress made on Award Number W81XWH-05-2-0015 for the third project year, from December 27, 2007 through December 26, 2008. The project, "Facilitating Smoking Cessation and Preventing Relapse in Primary Care: Minimizing Weight Gain by Reducing Alcohol Consumption," involves developing and testing a brief smoking cessation intervention for use in primary care settings. The intervention is intended to help participants stop smoking cigarettes and stay quit by use of motivational interviewing, behavioral counseling and nicotine replacement therapy with an emphasis on reducing alcohol consumption as a strategy for minimizing weight gain related to smoking cessation. Participants are randomly assigned to one of two groups: a Brief Counselor Assisted Program (BCAP), or a Self-Guided Program (SGP), with the nicotine patch and bupropion (Zyban) available to all participants. Participants in the BCAP attend two 30-minute clinic appointments and have two counseling sessions by phone over a period of 8-10 weeks, where tobacco cessation skills are integrated with weight and alcohol reduction strategies. Participants in the SGP receive, in addition to the medication, a pamphlet discussing the most effective behavioral change strategies for tobacco cessation, how to minimize weight gain, and how to plan for and deal with possible relapses. Current smokers at 3-month follow-up, blocked by original group assignment, are randomized either to receive no further counseling or to attend one clinic booster session focusing on dealing with their individual obstacles to change. All participants will be followed up for 12 months. The study addresses three research questions: (1) Does an alcohol reduction strategy designed to minimize weight gain produce higher smoking cessation rates than a control treatment? (2) Does participation in a tobacco cessation program that includes an alcohol reduction component lessen the risk of relapse? (3) Does providing a stepped care intervention (booster) for participants who initially are unsuccessful at stopping improve long-term tobacco cessation rates?

Body

The original Statement of Work was itemized for each investigator and consultant and by necessity, therefore, included considerable redundancy. To make this report better organized and easier to follow, we first discuss progress made toward objectives shared among the investigators. Following that, individual Statements of Work will be presented.

During the Project Year 4 our focus was on recruitment, running the treatment sessions, and gathering follow-up data as specified in the research protocol. As our recruitment rate had lessened considerably despite implementing a variety of strategies, early in Year 4 we requested and received a two year unfunded extension of the grant period, which allowed us to continue recruitment through Year 4. Recruitment continued to be slow for three reasons. First, deployments and the expectation of deployments impacted some possible subjects by making them unwilling to commit to be in a study at this time.

We do not know the number of potential subjects impacted in this regard, but we did hear statements to this effect from some potential subjects. Second, the availability of Chantix, which had little impact on the study when first approved by the FDA due to concerns that it might have a side effect of aggressive behavior, had a noticeable impact during Year 4 because some of the concern about side effects had lessened and also because it became known that by entering the Health and Wellness Center 8-session smoking cessation program, Chantix could be received. Late in the year, the Health and Wellness Center introduced a shortened version of their program (4-session) having yet further impact. We do not know the full number of potential subjects who did not enter this project because of the unavailability of Chantix (because some would never have had contact with us), but we do know that of the individuals we contacted for screenings, 48 did not follow through with the screening because Chantix was not available as part of the study. Of course, since the study was in progress when Chantix was approved by the FDA, it could not be incorporated into the research design. The third factor that made recruitment slow was that it continued to be the case that an unexpectedly high number of potential subjects did not meet alcohol consumption criteria (≥ 4 drinks per week). In fact, 593 of 1,296 individuals screened did not meet alcohol consumption criteria, and this amounted to 593 (65%) of the 906 who were screen outs. This was unexpected given the military survey data on which the study was planned. It is possible that underreporting occurred during the screening because active duty personnel were aware that if they reported what would be considered high levels of consumption, they would need to be referred to the base alcohol and drug treatment program. Since such a referral could have career consequences, underreporting of this sort could have occurred. It also would help explain the discrepancy between survey data and the relative lack of heavy drinking that was reported to us, in that the surveys provide anonymity whereas we were required to refer individuals with problems to treatment. As we had observed a lessening of recruitment over time from the Kelly Family Medicine Clinic that seemed to be related to many of their patients being continuing patients who had already been approached by us many times, we undertook several new initiatives to increase recruitment during Year 4. These efforts included placing approved advertising materials in several approved new locations, as well as staffing live recruitment tables at additional sites, including the North Central Federal Clinic and the Dunn Dental Clinic. We also sought to more actively recruit participants from the Brooke Army Medical Center (BAMC). We established contact with the tobacco cessation program staff and they agreed to directly refer interested persons to our study. We also presented a briefing to primary care staff and provided recruitment materials to be passed along to interested patients. Recruitment from was very little, however, most likely due to the distance between facilities (45 min drive). Our final sample consisted of 317 subjects, with 158 assigned to the BCAP group and 159 assigned to the SGP group.

In terms of preliminary findings, our early results continue to look very good. Because the study includes a nested assignment to a possible booster session if participants are assessed as smoking at three months after entry into the study, we are able to easily identify the cessation

rates (based on 7-day point prevalence, a standard way cessation is measured in smoking cessation studies). As of December, 2008, the BCAP group had a 46.0% cessation rate at 3-months, compared to a 34.5% rate for the SGP group. Also, our follow-up data collection rate at 3-months is running 91.5% which is exceptional and higher than expected. Data are being regularly double entered and verified by research assistants at Nova Southeastern University. Although we are slightly short of our targeted recruitment, our high rate of collection of follow-up data will be very helpful. We had anticipated a 20% attrition rate for follow-up, but it looks like we will end up with a rate close to 10%. For Project Year 5 our emphasis will be on completing remaining sessions for subjects recruited late in Year 4, continuing to collect follow-up data, data entry, and initial data analyses. With regard to data analyses, we plan during the spring to request a modification to our award (only internal re-budgeting will be involved) that will allow us more control over the data analyses, minimize the chance for errors, and provide a faster turn around. We also have submitted a proposal for a poster presentation at the annual meeting of the Research Society on Alcoholism in late May and we plan to submit a proposal for an oral presentation at the Military Health Research Forum to be held in Kansas City in late August. During the project year, manuscript planning and preparation will also be an important focus.

The following completes the body of this report in a more standard format, reporting achievement of benchmarks in the Statement of Work.

Mark B. Sobell, Ph.D.

1. Hire project team members: Completed Year 1.
2. Finalize formal protocol, manuals: Completed, see above.
3. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Completed, see above.
4. Monitor compliance with, and integrity of, the treatment protocols: Ongoing.
5. Monitor the quality control of all the data collection required for the project: Ongoing.
6. Generate reports on outcomes of each new patient cohort administered the treatment protocols, in collaboration with the biostatistician: This objective will become effective during Year 5 as sufficient data have been collected for statistical analyses.
7. Update previous reports with most recent patient cohort outcome data, in collaboration with the biostatistician: This objective will become effective during Year 5 as sufficient data have been collected for statistical analyses.
8. Develop and implement plan to recruit a total of 350-400 subjects into the project by Y04 M12. The plan will include continued on site recruitment at the Kelly Family Medical Clinic and the Wilford Hall Medical Center, use of occasional base wide emails, posters, and other methods of solicitation as approved by the Wilford Hall Medical Center IRB. In addition, on site recruitment will be established at the North Central Federal Outpatient Clinic in San Antonio. Extensive efforts to increase recruiting were undertaken during Year 4, in addition to the extension of the project period that allowed us to continue recruitment throughout the year. These efforts were successful in gaining a larger cohort, but we did not reach our objective of 350, ending with 317. The reasons why recruitment became so difficult have already been discussed. On the positive side, our follow-up attrition rate is running about half of what was

expected, and that will help increase the statistical power of our analyses as it is the number of persons for whom we have data that is critical to the analysis rather than the entire sample size.

9. Generate the final manuscripts of study results: This objective will be a focus of the latter part of Year 5 and of Year 6.

9. Disseminate results and materials produced by the study: This objective will become effective as the data analyses are completed.

Linda C. Sobell, Ph.D.

1. Hire project team members: Completed Year 1.

2. Finalize formal protocol, manuals: Completed, see above.

3. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Completed, see above.

4. Train personnel in project intervention: Completed.

5. Monitor compliance with, and integrity of, the treatment protocols: Ongoing.

6. Monitor the quality control of all the data collection required for the project: Ongoing.

7. Generate reports on outcomes of each new patient cohort administered the treatment protocols, in collaboration with the biostatistician: This objective will become effective during Year 5 as sufficient data have been collected for statistical analyses.

8. Oversee the conduct of project follow-up: Ongoing.

9. Generate the final manuscripts of study results: This objective will be a focus of the latter part of Year 5 and of Year 6.

10. Disseminate results and materials produced by the study: This objective will become effective as the data analyses are completed.

Lt. Col. Alan Peterson, Ph.D.

1. Review/coordinate IRB approvals: Completed.

2. Hire project team members: Completed Year 1.

3. Secure office space for WHMC grant staff: Completed.

4. Finalize formal protocol, manuals: Completed, see above.

5. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Completed, see above.

6. Coordinate the training of phone counselors this project: Completed.

7. Provide weekly clinical supervision of phone counselors and monitor compliance with, and integrity of, the treatment protocols: Ongoing.

8. Monitor the quality control of all the data collection required for the project: Ongoing.

9. Generate reports on outcomes of each new patient cohort administered the treatment protocols, in collaboration with the biostatistician: This objective will become effective during Year 5 as sufficient data have been collected for statistical analyses.

10. Update previous reports with most recent patient cohort outcome data, in collaboration with the biostatistician: Ongoing.

11. Supervise WHMC military and grant staff in assessment and intervention procedures: Ongoing.

12. Assist in developing and implementing a plan to recruit a total of 350-400 subjects into the project by Y04 M12. The plan will include continued on site recruitment at the Kelly Family Medical Clinic and the Wilford Hall Medical Center, use of occasional base wide emails, posters, and other methods of solicitation as approved by the Wilford Hall Medical Center IRB. In addition, on site recruitment will be established at the North Central Federal Outpatient Clinic in San Antonio. Extensive efforts to increase recruiting were undertaken during Year 4, in addition to the extension of the project period that allowed us to continue recruitment throughout the year. These efforts were successful in gaining a larger cohort, but we did not reach our objective of 350, ending with 317. The reasons why recruitment became so difficult have already been discussed. On the positive side, our follow-up attrition rate is running about half of what was expected, and that will help increase the statistical power of our analyses as it is the number of persons for whom we have data that is critical to the analysis rather than the entire sample size.
13. Generate scientific conference presentations of study preliminary results: Ongoing, with proposals for two presentations to be submitted this year.
14. Review/coordinate IRB amendments and annual reports: Ongoing.
15. Generate the final manuscripts of study results: This objective will be a focus of the latter part of Year 5 and of Year 6.
16. Disseminate results and materials produced by the study: This objective will become effective as the data analyses are completed.

Maj. Christopher Hunter, Ph.D.

1. Revise intervention manuals: Completed, see above.
2. Assist in finalization of assessment instruments: Completed, see above.
3. Assist in training of military and grant staff to work in the primary care setting: Completed.
4. Generate manuscripts of study results: This objective will be a focus of the latter part of Year 5 and of Year 6.

Maj. Christine Hunter, Ph.D.

1. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Completed, see above.
2. Assist in training of telephone counselors: Completed.
3. Assist in weekly supervision of phone counselors: Participates in weekly conference calls, but has separated from the military. Completed.
4. Generate manuscripts of study results: This objective will be a focus of the latter part of Year 5 and of Year 6.

Capt Jeffrey Goodie, Ph.D.

1. Finalize formal protocol manuals: Completed.
2. Assist in training staff to work in primary care setting: Completed.

3. Generate manuscripts of study results: This objective will be a focus of the latter part of Year 5 and of Year 6.

Lt.Col. Ann Hryshko-Mullen, Ph.D.

Dr. Hryshko-Mullen is one of three Wilford Hall Medical Center staff members who have been added to the research team after the Permanent Change of Station (PCS) of Capt. Jeffrey Goodie, Ph.D. in August 2005. Dr. Mullen is the Chief of the Clinical Health Psychology Service at Wilford Hall.

1. Maintained Wilford Hall office space for all grant staff personnel: Ongoing.
2. Coordinated with Lackland AFB Tobacco Cessation Program to limit any overlap or conflict with proposed study and ongoing Tobacco Cessation programs: Ongoing.
3. Manuals: Completed, see above.
4. Assist in training staff to work in primary care setting: Completed.
5. Generate manuscripts of study results: This objective will be a focus of the latter part of Year 5 and of Year 6.

Maj William Isler, Ph.D.

Dr. Isler has had a permanent change of station and is no longer associated with this project.

Capt Steve Schmidt, Ph.D.

Dr. Schmidt has had a permanent change of station and is no longer associated with this project.

Keith Haddock, Ph.D.

1. Provide consultation on development of database for study and computerize data entry: Completed, see above.
2. Oversee entry of project data, plan for statistical analyses: Ongoing.
3. Conduct statistical analyses, consult on interpretation of findings: This objective will become effective when the project database is sufficiently large to allow statistical analyses.
4. Generate manuscripts of study results: This objective will be a focus of the latter part of Year 5 and of Year 6.

Carlos Poston, Ph.D.

1. Provide consultation on development of database for study and computerize data entry: Completed, see above.
2. Oversee entry of project data, plan for statistical analyses: Ongoing.
3. Conduct statistical analyses, consult on interpretation of findings: This objective will become effective when the project database is sufficiently large to allow statistical analyses.

4. Generate manuscripts of study results: This objective will be a focus of the latter part of Year 5 and of Year 6.

Timothy Baker, Ph.D.

1. Provide consultation on smoking cessation treatment protocol and development of database: Completed, see above.
2. Help monitor integrity of study implementation: Ongoing.
3. Provide consultation on data analysis strategies: This objective will be a focus of the latter part of Year 5 and of Year 6.
4. Provide consultation on interpretation of results: This objective will be a focus of the latter part of Year 5 and of Year 6.

Key Research Accomplishments.

- Continued recruitment of participants into the project, achieving a final sample of 317 participants.
- Continued performance of treatment protocol with participants.
- Continued conduct of collection of follow-up data on participants, with a lower than expected rate of attrition.
- Continued required IRB approvals for project.
- Ongoing data entry into project database.
- Approval was gained to extend the project period for two years without additional funding. This allowed recruitment to continue which increased the final sample size.

Reportable Outcomes

Recruitment for the study was completed in December ,2008. Counseling sessions will continue through early March. A minimum of two presentations are planned during Project Year 5 to present three-month smoking cessation results with rates presently running 46.0% for the BCAP group and 34.5% for the SGP (control) group. These rates will change slightly as remaining cases come due for their three-month data collection, but sufficient data have been collected at this point to indicate that the BCAP group will have a higher cessation rate.

Conclusions

The project is continuing on schedule consistent with the unfunded extension of the project period. Recruitment has been completed, and we are in the process of completing the remaining counseling sessions. Follow-up data collection is proceeding very well with lower than expected attrition. Although the evaluation of outcomes awaits the completion of follow-up and statistical analyses, progress to date has demonstrated the feasibility of the treatment protocol.

References

None at this time.

Appendices

None for this report.